510(k) Summary

APR 2 7 2010

This 510(k) Summary of safety and effectiveness is being submitted in accordance with the requirements of SMDA 1990 and 21CFR807.92.

The Assigned 510(k) is: K093377

Applicant Information

Submitter's Name and Address:
Reliance Design & Manufacture Corp.
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Taiwan R.O.C.

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Summary Prepared: 07/06/2009

Trade Name: Polaris Contact Lens Case
Common Name: Contact Lens Case
Classification Name: Soft (hydrophilic) contact lens care products (886.5928)
Classification: Class II

Predicate Device: Contact Lens Case (Multiple Brand Names)
Applicant: Ningbo Kaida Rubber & Plastic Technology Co., Ltd.
Classification Name: Soft (hydrophilic) contact lens care products (886.5928)
Classification: Class II
510(k) Number: K071081

Device Description
Polaris Contact Lens Case is a product for the storage of soft (hydrophilic) and rigid gas permeable contact lenses. This device is intended for use with a contact lens solution to store the contact lenses, This product is not to be used in heat disinfection.

This device is manufactured in two variations: #101 and #201. The variants follow the same design principles and have the same intended use. The only differences are the dimensions and appearance between the two models. These variations do not affect the safety or effectiveness of the products' intended use.

The primary materials which compose the applicant device are ST757M and PT231M; they are produced by Taiwan Polypropylene Co., Ltd. ST757M is a translucent raw material and PT231M is an opaque white raw material. The Polymer 27A55 is produced by Kraton Polymers UK Ltd.

The volume of each of the two chambers in the applicant device #101 contact lens case is 4.5ml. The volume of each of the two chambers in the applicant device #201 contact lens case is 3ml. Contact lenses can be fully immersed into the chamber; both models can accommodate all lenses currently on the market.

Intended Use
Polaris Contact Lens Case is for the storage of soft (hydrophilic), rigid gas permeable, or hard contact lenses. It is to be used with chemical disinfectants only. It is not to be used in heat disinfection.

Technology Characteristics
Polaris Contact Lens Cases #101 & #201 are products for the storage of soft (hydrophilic) and rigid gas permeable contact lenses. They were manufactured in formulation with Ningbo Kaida Rubber & Plastic Technology Co., Ltd Contact Lens Case (FDA 510(k) K071081 -- currently in commercial distribution).

Non-Clinical Performance Data

Biocompatibility Tests

Polaris Contact Lens Cases have been evaluated in accordance with Part 10993 of the International Standard Organization (ISO). Standard tests administered include:

- ISO 10993-5:1999 Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity. The test article did not induce cytotoxic effects and did not inhibit cell proliferation after exposed for 24 to 48 hours in L929 colorectal carcinoma cells.

- ISO10993-10 (2002) Biological Evaluation of Medical Devices – Tests of Irritation and Delayed-Type Hypersensitivity.
    - Under the conditions of this study, the test article was injected with 0.9% extracted Sodium Chloride; there was no evidence of delayed dermal contact sensitization in guinea pigs.
    - There was no deviation from the approved study protocol and no adverse problems that would affect the integrity of the results or the interpretation of our conclusion.

- ISO 10993-11:2006 Biological evaluation of medical devices - Tests for Systemic Toxicity. All data generated from this study will be used as safety criteria for human exposure.

Clinical Performance Data
Polaris Contact Lens Cases have not been studied in a clinical setting.

Table I – Technological Characteristics Summary

Company / Items	Reliance Design & Manufacture Corp.	Ningbo Kaida Rubber & Plastic Technology Co., Ltd.	Result
Product Name	Polaris Contact Lens Case	Contact Lens Case (Multiple Brand Names) (K071081)	
Classification Advisory Committee	Ophthalmic	Ophthalmic	Same
Regulation Number	886.5928	886.5928	Same
Product Code	LRX	LRX	Same
Intended Use	For storage of soft (hydrophilic), rigid gas permeable or hard contact lenses. Used for storage during chemical disinfection only. Do not use during heat disinfection.	The Applicant contact lens case is a lens care product to be used by the contact lens wearer or practitioner for storing contact lenses while not being worn. The applicant device is not designed for heat disinfecting system. Use only with chemical disinfection.	Same
Indications	For storage of soft (hydrophilic), rigid gas permeable or hard contact lenses. Use for storage during chemical disinfection only. Do not use during heat disinfection.	Storage and Disinfection of Soft, Rigid Gas Permeable or Hard	Same
Materials	Taiwan Polypropylene Co.,LTD. Polypropylene ST775M & PT231M	SK Corporation Polypropylene (PP) R370 Y with certificated quality	Same
Composition(%)	- Polyolefin > 95% - Mixture < 5%	Unknown	N/A
Comparison	Composition of predicate device was not listed in predicate 510(k) Summary.		
Size	#101: Length: 63.77mm, Weigh: 33.31mm, Height: 16.00mm #201: Length: 67.97mm, Weigh: 31.97mm, Height: 21.50mm	Length: 62.96mm Weigh: 30.90mm Height: 16.38mm	Different
Volume	#101: 4.5 ml each side #201: 3.0 ml each side	4.2 ml each side	Different
Comparison	Although the volumes of #101 & #201 contact lens cases are different than the predicate, the sizes of all contact lenses on the market are no larger than 1.4 cm diameter x 0.35 cm height, thus, any contact lens on the markets can be fully immersed into the chambers. These differences are not critical nor do they affect the safety or effectiveness of the devices.		
Biocompatibility Tests Performed	■ ISO 10993-5:1999 - In vitro cytotoxicity ■ ISO10993-10:2002 - Tests of Irritation and Delayed-Type Hypersensitivity. ■ ISO 10993-11:2006 - Tests for Systemic Toxicity.	■ In Vitro Cyto-toxicity ■ Delayed-type Hypersensitivity ■ Eye Irritation ■ Systemic Toxicity	Same

Conclusion

After comparison, it has been determined that Polaris Contact Lens Cases #101 & #201 have the same intended use, effectiveness, safety, and biocompatibility as the Ningbo Kaida Rubber & Plastic Technology Co., Ltd. Contact Lens Case (Multiple Brand Names) (K071081).

The size and volume are different than the predicate. The volume of each chamber in applicant device #101 contact lens case is 4.5 ml (2.3 cm square x 0.85 cm depth). The volume of each chamber in #201 contact lens case is 3 ml (2.1 cm diameter x 0.86 cm depth). Although the volumes of #101 & #201 contact lens cases are different than the predicate, the sizes of all contact lenses on the market are no larger than 1.4 cm diameter x 0.35 cm height, thus, any contact lens on the markets can be fully immersed into the chambers. These differences are not critical nor do they affect the safety or effectiveness of the devices.

The applicant performed biocompatibility testing based on ISO 10993 standards for contact lens cases. Additionally, the applicant performed leakage tests on each variant of the contact lens case. The result of testing and evaluation supports the claim of Polaris Contact Lens Case as the substantial equivalent of Ningbo Kaida Rubber & Plastic Technology Co., Ltd's. Contact Lens Case (Multiple Brand Names) (K071081).

End Summary

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Reliance Design & Manufacturing Corp.
c/o Underwriters Laboratories, Inc.
Mr. Marc M. Mouser
2600 NW Lake Rd.
Camas, Washington 98607-9526

APR 27 2010

Re: K093377
Trade/Device Name: Polaris Contact Lens Case
Regulation Number: 21 CFR 886.5928
Regulation Name: Soft (hydrophilic) contact lens care products
Regulatory Class: Class II
Product Code: LRX
Dated: April 9, 2010
Received: April 12, 2010

Dear Mr. Mouser:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Alexander

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K093377

Device Name: POLARIS CONTACT LENS CASE

Indication for Use :

For storage of soft (hydrophilic), rigid gas permeable, and/or hard contact lenses. Use for storage during chemical disinfection only. Do not use during heat disinfection.

Prescription Use ____ ***AND/OR*** *Over-The-Counter Use* __X__

(Part 21 CFR 801 Subpart D) *(Part 21 CFR 801 Subpart C)*

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)

Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

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